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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,438	04/13/2001	Paul G. Alchas	P-4498P2	2953

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EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 09/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,438

Applicant(s)

ALCHAS ET AL.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2002 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-93 is/are pending in the application.

4a) Of the above claim(s) 11-16, 19-23, 36-38, 40, 43-47, 59, 60, 66-70 and 74-93 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17, 18, 24-35, 39, 41, 42, 48-58, 61-65 and 71-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 13 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,6.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

U.S. Patent and Trademark Office
PTO-326 (Rev. 04-01)

Office Action Summary

Part of Paper No. 9

DETAILED ACTION
Election/Restrictions

Applicant's election of species I (figs. 1-3) and subspecies A in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11-16, 19-24, 36-38, 40, 43-47, 59-60, 66-70 and 74-93 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

An action on the merits now follows.

Information Disclosure Statement

The information disclosure statement filed 4/13/01 and 01/29/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Applicant is requested to submit copies of the patents or publications which have not been considered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the plane generally

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perpendicular to the axis within about 5 degrees and about fifteen degrees must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

The specification is replete with spelling error of Luer. Applicant has recited "Leur Lok", "Leur fit", Leur Slip". See below.

The attempt to incorporate subject matter into this application by reference to a copending application without the serial number/patent number is improper because it can not be relied upon. Further, any amendment introduced after the initial filing date may be construed as new matter if it is not supported as originally filed.

On page 18, line 9, reference numeral disclose a tapered bottom "21", however, fig. 2 disclose 21 as a reservoir.

Appropriate correction is required.

Claim Objections

Claims 2-10,17-18,24-26,28-35,39,41-42,48-50,52-58,61-65,71-73, 18 are objected to because of the following informalities:

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Applicant is requested to amend "said needle forward tip" in line 13 to "said needle cannula forward tip" for consistency. ^{c./}_^

In claims 18 & 65, "Leur" should be spelled "Luer".

For all the dependent claims, applicant is suggested to refer to the preamble as "The assembly" instead of "An assembly".

Claim 54 and 61 are the same. It is unclear what applicant is intending to further limit.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 17-18, 24-26, 27-35, 39, 41-42, 48-50, 51-58, 61-65, 71-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because "the vaccine" lacks proper antecedent basis in line 16. A "substance" has only been functionally recited.

Claims 24 ,48 and 71 are vague and indefinite because it is unclear whether applicant is intending to positively recite "a rearward cap" when applicant refers to "said caps".

Claims 25, 49 and 72 are indefinite because " said rearward cap" lacks proper antecedent basis.

Claim 27 is vague and indefinite because "the substance" in line 15 lacks proper antecedent basis. A "vaccine " has only been functionally recited.

Claim 39 is indefinite because "said adhesive " lacks proper antecedent basis.

Claim 51 is vague and indefinite because the preamble functionally recites injecting of vaccines in line 3 and in lines 10 and 13, applicant functionally recites a substance. Applicant is requested to be consistent with the claim language. Further, applicant is requested to be consistent with the "needle cannula" and "needle" terminology used in the claim. See lines 4,5,7,10 of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-5, 17, 18, 24-26, 51-53, 55, 64-65, 71-73 are rejected under 35

U.S.C. 102(e) as being anticipated by Gross et al. (U.S. Patent No. 6,099,504).

Gross et al. disclose an intradermal needle assembly comprising a hub portion, a needle cannula (15), and a limiter portion (20) surrounding the needle cannula wherein the hub portion is separated piece than the hub portion. Gross et al disclose the needle cannula extending beyond the flat skin engaging surface of the limiter portion by 1-3 mm which encompass the approximately 0.5 to 3 mm of applicant's claimed limitation.

With respect to claims 2-3 and 51, the Examiner is taking the position that Gross anticipates the limitations within the broadest interpretation. And further, inasmuch as applicant has shown the limitations of the angles, Gross shows the same.

With respect to claims 17 and 64, Gross anticipates the claim since applicant has only inferentially claimed the substance/influenza vaccine and has not been positively recited.

With respect to claim 5 and 53 Gross et al. teach in col. 6, lines 61-65 that the upper lip 26 of the limiter portion/sleeve is abutting against the flange of the mounting body /hub to limiting the length the cannula extends beyond the skin engaging surface.

With respect to claims 18 and 65, applicant has only functionally claimed the needle assembly attachable to a prefillable container with a Luer fit. Gross et al. show the needle assembly attachable to the prefillable container. The Leur fit does not further

limit the claim since it has only been only inferentially claimed. However, Gross device would be capable of it.

With respect to claims 24-25 and 71-72, Gross et al. teach a forward (42) and rearward cap (11). See fig. 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26 and 73 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gross et al. (U.S. Patent No./ 6,099,504).

See rejection above. If it isn't deemed inherent that the outer diameter of the skin engaging surface is at least 5mm, then it would have been obvious to one of ordinary skill in the art to modify the size as a mere design choice because Applicant has not disclosed that modifying the outer diameter provides an advantage, is used for a particular purpose, or solves a stated problem. One ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any size since it would perform the same function equally well considering that the skin engaging surface is present to limit the depth of the needle. Further, a modification would have involved a mere change in the size of a component. A change in size is

generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 6-9, 27-34, 39, 41-42, 48-50, 54-57, 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al. (U.S. Patent No. 6,099,504) in view of Hjertman and further in view of Dragosits et al. (U.S. Patent No. 5,147,328).

Gross et al. disclose the invention substantially as claimed. See above. With respect to claims 48-49, see fig. 10 of Gross et al. With respect to the claims which are similar, if it hasn't been addressed directly it is deemed to be rejected in a similar logical manner as those claims with the same limitations.

Gross et al. does not show a hub portion having a throat. Applicant has not disclosed that modifying the hub portion with a throat provides an advantage, is used for a particular purpose, or solves a stated problem. Hjertman et al. disclose a hub having a throat for receiving the prefillable container in the analogous art of limited depth penetration. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the hub portion of Gross et al. with a throat/lumen for receiving the container as taught by Hjertman since it would perform equally well to secure to the cartridge/container in place. Further it would have been an obvious design choice since it is well known in the art to have a lumen in the hub for retaining/receiving/securing the needle to the container.

With respect to claims 7-9, 32-34, 39, 61-63, Gross et al. disclose the needle cannula fixedly attached to the hub portion. However, Gross is silent to the attachment being an epoxy curable with ultraviolet light. Dragosits et al. disclose a needle secured

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to the hub by various means such as mechanical connection, adhesives such as heat curable and ultraviolet curable epoxy adhesives. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the needle-hub attachment with an ultraviolet curable epoxy adhesive as taught by Dragosits et al. to better secure the attachment between the needle and the hub.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 27, 51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,32 of copending Application No. 09/417,671. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are a broader recitation of the invention than that of the pending issued application, including all of the same limitations. The claims of the application claim an intradermal needle assembly comprising a hub portion, a needle cannula supported/affixed by the hub

portion and having a forward tip away from the hub portion and a limiter portion surrounding the needle cannula and the limiter having a generally flat engaging surface wherein the needle forward tip extends beyond the skin engaging surface by a distance of approximately 0.5mm to 3.0 mm. The pending issued claims recite a hypodermic needle assembly comprising a hub portion, a needle supported by the hub portion and a forward end extending away from the hub portion and a limiter portion that surrounds the needle and the limiter having a flat skin engaging surface wherein the needle forward end extends beyond the skin engaging surface from approximately 0.5mm to 3.0mm. Since a broad interpretation of the needle cannula includes needle, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the pending patent.

With respect to claim 27 of the application, since a broad interpretation of the hub portion having a throat includes hub portion, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the pending patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 10,35,58 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Reich (5,672,883) shows a forward and rearward cap.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


LoAn H. Thanh
Examiner
Art Unit 3763

LT
September 22, 2002